

REMARKS

Claims 1-10 and 12 are pending after entry of the amendments set forth herein. Claims 1, 4, 8 and 9 are amended. Support for these amendments is found throughout the specification as originally filed, for example, at page 4, lines 25-28.

No new matter is added. As such, the Examiner is requested to enter the above amendments.

REJECTIONS UNDER §103(A)

I. Claims 1-3 and 5-6 were rejected under 35 U.S.C. 103(a) as being unpatentable over Kim (2002) Autonomic Neuroscience 102:8-12 in view of Donovan (U.S. Patent Application Publication 2001/0023243).

Claim 2-3 and 5-6 depend from Claim 1, and thus contain all of the elements of Claim 1. Claim 1 as amended recites the use of a botulinum toxin to achieve a "reversible sympathetic block" in the treatment of pain. Applicants submit that the cited art does not make obvious the pending claims because neither the primary reference nor the secondary reference teaches that administration of botulinum toxin will provide for the reversible inhibition of sympathetic nerve transmission, i.e., a reversible sympathetic block, in the treatment of pain.

The primary reference, Kim *et al.*, teaches the use of botulinum toxin A as a neurolytic agent. Kim *et al.* teach "the possible clinical use of BA as a neurolytic agent was evaluated" (abstract, para. 2) and "In conclusion . . . this toxin may be used in the case of sympathetically maintained pain control as a sympatholytic" (abstract, para. 4). The dictionary definition of neurolysis (The American Heritage® Medical Dictionary Copyright © 2007, 2004 by Houghton Mifflin Company) is:

1. The breaking down or destruction of nerve tissue, especially as a result of disease.
2. The surgical freeing of a nerve from inflammatory adhesions.

Consistent with this, Kim *et al.* teaches that "conventional neurolytic agents destroy nerve fibers nonselectively" (abstract). Thus, Kim *et al.* teaches that neurolytic agents are agents that kill nerve fibers. It is well understood in the art that death is not reversible. Accordingly, one of ordinary skill in the art would not be able to predict with any expectation of success from the teachings of Kim *et al.* that botulinum toxin will provide for a reversible sympathetic block, let alone a reversibly sympathetic block in the treatment of pain.

The secondary reference, Donovan, does not remedy the deficiencies of the primary reference. Donovan was cited for teaching administration of botulinum toxin to sympathetic

ganglia by percutaneous injection (Examiner's Answer, p. 6, l. 17-18). However, relevant to the deficiencies of Kim *et al.*, Donovan is silent on administration of botulinum toxin to provide for a reversible sympathetic block, let alone a reversible sympathetic block for the treatment of pain.

Because neither Kim *et al.* nor Donovan teaches or suggests that administration of botulinum toxin to ganglions will provide for a reversible sympathetic block in the treatment of pain, Kim *et al.* in view of Donovan does not make obvious the pending claims.

In maintaining this rejection, the Board of Appeals asserted on page 5, lines 16-24, that:

Appellants cite to a dictionary definition of "neurolysis" (*see* App. Br. 4), but they do not explain why a "sympathetic block for an extended period of time" is not achieved by destroying the neuron, especially given that Appellants' claims do not limit the duration of the block. In fact, Appellants' specification states that "neurolytic techniques have also been used as a sympathetic block." (Spec. ¶ [09]). Thus, the broadest reasonable interpretation of the claim term "sympathetic block" would include a block produced by a neurolytic agent. We are not persuaded that Kim fails to teach that BTA can achieve a sympathetic block, as claimed.

As discussed above, the claims as amended now recite that the sympathetic block provided by the botulinum toxin is *reversible*. Accordingly, Applicants believe they have adequately addressed the Board's concerns.

In view of these amendments and remarks, reconsideration and withdrawal of the rejection is respectfully requested.

II. Claims 1-3 and 5-7 were rejected under 35 U.S.C. 103(a) as being unpatentable over Kim (2002) in view of Donovan 2001/0023243 as applied to claims 1-3 and 5-6 above, and further in view of Erickson (1993. Radiology 188:707-709).

As discussed above, Claims 1-3 and 5-7 recite the use of a botulinum toxin to achieve a "reversible sympathetic block" in the treatment of pain. Applicants submit that the cited art does not make obvious the pending claims because neither the primary reference nor the secondary references teach that administration of botulinum toxin will provide a reversible sympathetic block in the treatment of pain.

As evidenced above, Kim *et al.* in view of Donovan do not teach or suggest that botulinum toxin will provide for a reversible sympathetic block, let alone a reversible sympathetic block for the treatment of pain, as recited in the pending claims. The secondary reference, Erickson *et al.*, does not remedy this deficiency. Erickson *et al.* were cited for teaching the administration of local anesthetics, including lidocaine, bupivacaine, and buprenorphine, as reversible sympathetic blocks (Examiner's Answer, p. 4, l. 24-25). However, relevant to the deficiencies of Kim *et al.* in view of Donovan *et al.*, Erickson *et al.* are silent on administration of botulinum toxin to provide for a reversible sympathetic block, and more particularly, in the treatment of pain.

Because Kim *et al.*, Donovan, and Erickson *et al.* do not teach or suggest that administration of botulinum toxin will provide for a reversible sympathetic block in the treatment of pain, Kim *et al.* in view of Donovan and Erickson *et al.* do not make obvious the pending claims. Reconsideration and withdrawal of the rejection is respectfully requested.

III. Claims 1-6 were rejected under 35 U.S.C. 103(a) as being unpatentable over Kim (2002) in view of Donovan 2001/0023243 as applied to claims 1-3 and 5-6 above, and further in view of Brushey (U.S. Patent Application Publication 2001/0056275, published 27 December 2001).

Claims 1 and 4, from which the remaining claims in this rejection depend, recite the use of a botulinum toxin to achieve a "reversible sympathetic block" in the treatment of pain. Applicants submit that the cited art does not make obvious the pending claims because neither the primary reference nor the secondary references teach that administration of botulinum toxin will provide for a reversible sympathetic block in the treatment of pain.

As evidenced above, Kim *et al.* in view of Donovan do not teach or suggest that botulinum toxin will provide for a reversible sympathetic block, let alone a reversible sympathetic block for the treatment of pain, as recited in the rejected claims. The secondary reference, Brushey, does not remedy this deficiency. Brushey was cited for teaching that when sympathetic pain is present in the lower extremities, the splanchnic nerve should be blocked (Examiner's Answer, p. 5, l. 19-21). However, relevant to the deficiencies of Kim *et al.* in view of Donovan, Brushey is silent on botulinum toxin, and more particularly, that botulinum toxin will provide for a reversible sympathetic block in the treatment of pain.

Because Kim *et al.*, Donovan, and Brushey do not teach or suggest that administration of botulinum toxin will provide for a reversible sympathetic block in the treatment of pain, Kim *et*

al. in view of Donovan and Brushey do not make obvious the pending claims. Reconsideration and withdrawal of the rejection is respectfully requested.

IV. Claims 1-3, 5-6, 8-10, and 12 were rejected under 35 U.S.C. 103(a) as being unpatentable over Henard (1982. Arch Mal Coeur 75(11):1317-1320, cited on IDS filed 22 February 2007) in view of Kim (2002) and Donovan 2001/0023243.

Claims 1, 4, 8, and 9, from which the remaining claims in this rejection depend, now recite the use of a botulinum toxin to achieve a "*reversible* sympathetic block." Applicants submit that the cited art does not make obvious the pending claims because neither the primary reference nor the secondary reference teaches that administration of botulinum toxin will provide for the reversible inhibition of sympathetic nerve transmission, i.e., a reversible sympathetic block, in the treatment of pain (Claims 1 and 4), cardiovascular conditions (Claim 8), and peripheral vascular disease (Claim 9).

The primary reference, Henard *et al.*, was cited for teaching treatment of coronary vasospasm by homolateral thoracic sympathectomy, i.e. surgical removal of sympathetic ganglion (Examiner's answer, p. 6, l. 4-10) However, relevant to the pending claims, Henard *et al.* does not teach or suggest *reversible* inhibition of sympathetic neuron signaling, let alone that botulinum toxin will provide for such reversible inhibition, or that such reversible inhibition will be useful in the treatment of pain, cardiovascular conditions, and peripheral vascular disease, as recited in the pending claims.

The secondary references do not remedy the deficiency of the primary reference. As evidenced above, the secondary references of Kim *et al.* and Donovan also do not teach or suggest that botulinum toxin will provide for reversible sympathetic block, let alone a reversible sympathetic block in the treatment of pain, cardiovascular conditions, and peripheral vascular disease.

Because Henard, Kim *et al.* and Donovan do not teach or suggest that administration of botulinum toxin will provide for a reversible sympathetic block in the treatment of pain, cardiovascular conditions, and peripheral vascular disease, Henard in view of Kim *et al.* and Donovan do not make obvious the pending claims. Reconsideration and withdrawal of the rejection is respectfully requested.

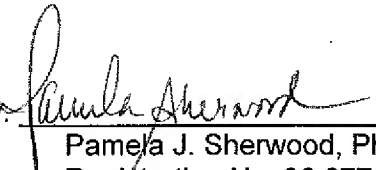
CONCLUSION

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.


The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number STAN-332.

Respectfully submitted,
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